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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,909

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Boris Y. Shekunov

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RANKIN, HILL & CLARK LLP
23755 Lorain Road - Suite 200
North Olmsted, OH 44070-2224

EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,909	Applicant(s) SHEKUNOV ET AL.	
	Examiner Casey S. Hagopian	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/21/2006 5/3/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-10 and 13-18) in the reply filed on 2/26/2010 is acknowledged. Applicant cancelled the non-elected claims. Thus, claims 1-10 and 13-18 are currently pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10, 13 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nielsen et al. (USPN 5,716,558, hereinafter "Nielsen") as evidenced by Engelsberg (USPN 5,821,175).

Nielsen teaches a method of producing solid particles, the particles comprising an organic solvent, a supercritical fluid including carbon dioxide and ethane, and an excipient including polyesters (Abstract; columns 1-4; col. 8, lines 23-40). Nielsen also teaches a milling device (i.e. a sprayer or jet) and particle sizes of greater than about one micron (col. 2, lines 17-18). Nielsen also exemplifies a particular average particle size of 21 microns (col. 13, lines 32-33). Nielsen teaches temperatures below 25°C to produce the solid particles (e.g., Example 2). Nielsen also discusses depressurization

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in the spray orifice (col. 10, line 39). It is noted that while Nielsen does not discuss all of the particulars of supercritical fluid technology, one of ordinary skill in the art would possess the knowledge of the specifics of supercritical fluid technology. For instance, supercritical fluid technology consists of using frozen gas as evidenced by USPN 5,821,175, see col. 4, lines 13-15. Also, the instant specification at paragraph [0008] states "expansion of the supercritical fluid is the force for this particle micronization and also produces a porous network within the solid particles (i.e., foaming)" which indicates that expansion of the supercritical fluid necessarily creates foaming and porosity. Further, at paragraph [0015] of the instant specification it is stated that "the supercritical fluid-saturated melt is expanded across a pressure drop, typically through a nozzle" which effectively suggests that as the melt travels through a nozzle, it necessarily experiences a pressure drop and expands.

Thus, the implicit and explicit teachings of Nielsen render the instant claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (USPN 5,716,558, hereinafter "Nielsen") as evidenced by Engelsberg (USPN 5,821,175).

Nielsen teaches the elements discussed above including optimizing the spray temperature such that if it is desired for the solvent to evaporate more rapidly, a higher spray temperature is needed (col. 10, lines 7-22).

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Nielsen is silent to “extracting the solvent from the melt using supercritical fluid as an extracting agent prior to the expanding step” and “the solid porous mass is milled before the temperature of the solid porous mass is permitted to rise to or above 25°C”.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the temperature by way of routine experimentation with a reasonable expectation of success because the prior art teaches modifying the temperature and how the modification affects the particulates. Also, one of ordinary skill in the art would be apprised of the knowledge that the workable temperature range would be directly dependent on the materials used including the particular excipients, supercritical fluid, solvent, etc. and subsequently would be able to obtain the ideal temperatures by way of routine experimentation depending on the desired result.

Thus, the teachings of Nielsen render the instant claims obvious.

Conclusion

All claims have been rejected; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/
Examiner, Art Unit 1615

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1615